UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE BIOGEN IDEC, INC. SECURITIES LITIGATION	:	Civil Action No. 05-10400-RCL

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED CLASS ACTION COMPLAINT

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES **PAGE(S)**

STATUTES **PAGE(S)**

OTHER AUTHORITIES **PAGE(S)**

PRELIMINARY STATEMENT

On October 13, 2006, Plaintiffs filed a 149-page, 435-paragraph amended complaint (the "Amended Complaint") asserting violations of the federal securities laws against Biogen Idec and certain of its current and former officers. The Amended Complaint is far from the "short and plain statement of the claim showing that the pleader is entitled to relief" contemplated by the Federal Rules. Fed. R. Civ. P. 8. "To be sure, the complaint is lengthy-but prolixity is neither a substitute for, nor a guarantor of, specificity." Royal Bus. Group, Inc. v. Realist, Inc., 933 F.2d 1056, 1065 (1st Cir. 1991) (affirming dismissal of complaint for failure to allege fraud with particularity).

Notwithstanding the prolix nature of the Amended Complaint -- much of it merely quotes publicly-available documents -- it fails in multiple respects to meet the pleading requirements for a federal securities fraud suit. Despite more than eighteen months of trying to drum up a claim of fraud, Plaintiffs selective recitation of purported events presents a demonstrably incomplete and misleading story. When the story is presented in context (as it was to numerous federal agencies and expert panels), Plaintiffs' claim of securities fraud is exposed as nothing more than impermissible "fraud by hindsight." The Amended Complaint fails as a matter of law and should be dismissed.

On February 28, 2005, Biogen Idec announced that it was voluntarily suspended the marketing of TYSABRI® -- a biological medicine approved as treatment for relapsing forms of a particularly debilitating disease: multiple sclerosis ("MS").[1] That voluntary suspension occurred after two patients in ongoing MS clinical trials were diagnosed with progressive

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[1] TYSABRI® is also known in the medical literature as α4-integrin, Antegren and natalizumab. The trademarked name of TYSABRI® is used in this memorandum.

multifocal leukoencephalopathy ("PML") -- a rare disease of the central nervous system. In conjunction with the United States Food and Drug Administration (the "FDA"), Biogen Idec and Elan Pharmaceuticals, Inc. ("Elan") embarked on a year-long comprehensive safety review of all data in the Phase III TYSABRI® clinical trials -- including trials in MS, Crohn's Disease ("Crohn's"). Upon the completion of that comprehensive safety review, on June 5, 2006, the FDA approved the reintroduction of TYSABRI® as a treatment for relapsing forms of MS. Because of the potential risk of PML, patients and their physicians must enroll in a risk management plan before receiving TYSABRI®. In addition, TYSABRI®'s revised package insert (or label) contains a prominent warning concerning the increased risk of PML associated with TYSABRI® treatment.

Plaintiffs' entire case is predicated upon their conclusory contention that Defendants "knew" but failed to disclose that TYSABRI® "turns off" the immune system, making it a "certainty" that patients treated with TYSABRI® would develop so-called "opportunistic infections." (Am. Compl. ¶¶ 97-98.) The Amended Complaint, however, omits the fact that TYSABRI® was voluntarily suspended solely because of the specific observance of PML, not due to an increased risk of unidentified "opportunistic infections." Further, the revised package insert contains a prominent warning (a so-called "black box" warning) concerning the increased risk of PML, not of unidentified "opportunistic infections." There is nothing in the Amended Complaint sufficient to demonstrate that any Defendant (or anyone else) "knew" that TYSABRI® would lead to PML, nor could there be.

Another example of the Amended Complaint's omissions is demonstrated in the allegations concerning safety events that Plaintiffs claim were observed in patients participating in the TYSABRI® clinical trials over several years. Plaintiffs allege that Biogen Idec and Elan observed "at least sixty opportunistic infections" (id. ¶ 153), when in fact the very documents

incorporated into the Amended Complaint and relied upon by Plaintiffs make plain that only 8 "opportunistic infections" were experienced in patients treated with TYSABRI®.

Notably, as to the "sixty opportunistic infections" Plaintiffs allege occurred, Plaintiffs' allegations are silent as to critical particular "facts" such as when those purported opportunistic infections were observed, when they were communicated to any Defendant, which clinical trials they were observed in and what treatment was the patient taking when it occurred (i.e., was the patient taking TYSABRI® or placebo -- to say the least, that is a critical difference). Also absent from the Amended Complaint are any allegations as to the causality assessment of any specific serious adverse event; in other words, did the patient's treating physician diagnose the adverse event as related or caused by TYSABRI®? The Amended Complaint never says. Absent particularized allegations of relatedness, Plaintiffs' conclusory assertions about such adverse events are meaningless.

Yet a further example of the Amended Complaint's fatal omissions is demonstrated in the allegations surrounding scienter for defendants Dr. Rastetter, Mr. Mullen, Dr. Adelman and Mr. Rohn. Plaintiffs place great emphasis on the fact that those defendants traded Biogen Idec securities during the putative class period. (Id. ¶¶ 387-91.) According to the Amended Complaint, those defendants' stock sales "were strategically timed to coincide with key events" (id. ¶ 394), and that conclusion gives rise to a strong inference of scienter. Remarkably, however, Plaintiffs omit the publicly available fact that the overwhelming majority of those sales (more than 80%) were made pursuant to written stock trading plans adopted pursuant to SEC Rule 10b5-1! (That Plaintiffs could not find room to include that matter-of-public-record fact in their lengthy Amended Complaint is emblematic of the misleading and selective nature of the allegations.) The decisions to sell those shares were made months prior, negating -- as a matter of law -- any inference of intent Plaintiffs purport to draw from them.

In addition to failing to disclose the existence of those trading plans, Plaintiffs also neglect to mention the public-record fact that Mr. Rohn announced his retirement during the putative class period. It is well-settled that stock trading by a corporate executive in advance of a retirement is not suspicious and does not give rise to any inference of scienter.

* * *

The Amended Complaint should be dismissed for multiple, independently dispositive reasons.[2]

First, the Amended Complaint fails to allege securities fraud with the requisite particularity. Although required to do so, the Amended Complaint never specifies with particularity all facts supporting what Defendants purportedly knew and why Defendants' statements were false at the time they were made. Instead, Plaintiffs conclusorily claim that Defendants ignored purported "red flags" concerning the risks associated with TYSABRI®, but nowhere explain how those hypothetical discussions warned Defendants of a risk of PML. Indeed, none of those concerns even mentioned the possibility of PML.

Similarly deficient are Plaintiffs' allegations that Defendants failed to disclose safety data to the FDA. Plaintiffs base that claim on a single comment by the FDA during the approval process that the reported events do not appear to be the result of opportunistic pathogens, but that comment was based on data gathered long before the completion of the clinical trials. Plaintiffs' conclusory assertion that numerous opportunistic infections were observed during the clinical trials -- without any effort to particularize when those experiences

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[2] The Amended Complaint purports to assert claims against Biogen Idec and the individually named defendants (except Mr. Bucknum) pursuant to Section 10(b) of the Securities Exchange Act of 1934 (15 U.S.C. §§ 78a et seq.) (the "Exchange Act"), against all individually named defendants (except Mr. Bucknum) pursuant to Section 20(a) of the Exchange Act and against all individually named defendants pursuant to Section 20(A) of the Exchange Act.

occurred -- is itself dispositive of Plaintiffs' allegations that Defendants withheld safety event information from the FDA.

Second, the Amended Complaint should be dismissed for the independent reason that Plaintiffs' allegations do not provide a strong inference of scienter. The Amended Complaint's allegations of knowledge are conclusory, and the generalized allegations of stock sales and motives to enhance bonus compensation or increase profits have been repeatedly and uniformly rejected by courts in this Circuit (and others) as insufficient to infer fraudulent intent; let alone the requisite strong inference.

Third, Defendants' forward-looking statements identified in the Amended Complaint as false and misleading qualify for dispositive protection under the Private Securities Litigation Reform Act of 1995's (the "PSLRA") multiple safe harbor provisions. All of those forward-looking statements were expressly identified as such, and are accompanied by meaningful cautionary language. In addition, all of Defendants' forward-looking statements are non-actionable under the separate, and independent, "known falsity" safe harbor because Plaintiffs have failed to adequately allege that any forward looking statement was made with actual knowledge of its falsity.

Finally, the Section 20(a) (control person liability) and Section 20(A) (insider trading) claims also should be dismissed because there is no actionable predicate Exchange Act claim stated in the Amended Complaint. Further, the Section 20(a) claim should be dismissed for the independent reason that Plaintiffs have not even attempted to allege any culpable participation by any of the individually named defendants to demonstrate their contemporaneous knowledge or participation in any purported violation of the securities laws.

ALLEGATIONS AND BACKGROUND[3]

TYSABRI® was discovered in or about the early 1990s by scientists at Athena Neurosciences to "selectively inhibit immune cells from leaving the bloodstream and to prevent these cells from migrating into chronically inflamed tissue as occurs in a variety of inflammatory diseases."[4] (2/18/04 Press Release, App. Ex. 1; see also Am. Compl. ¶¶ 63, 64.) Because TYSABRI®'s mechanism of action involves selectively inhibiting the body's immune response, it is categorized as an immunomodulator. (Medical Review at 13-14.)

Elan And Biogen, Inc. Enter Into A Collaboration Agreement

In the mid-1990's, Elan acquired Athena Neurosciences, and continued to develop TYSABRI®. (Am. Compl. ¶ 64.) On August 17, 2000, Biogen Idec's predecessor (Biogen, Inc.) and Elan Pharma International Limited entered into a collaboration agreement for the development and marketing of TYSABRI®. (Id. ¶ 68.) Plaintiffs allege that pursuant to that collaboration agreement (the "Collaboration Agreement"), Elan delegated to Biogen, Inc. the management of all TYSABRI® clinical trials involving patients with MS, while Elan retained management responsibilities for clinical trials in all other indications, including clinical trials for Crohn's. (Id. ¶ 82.)

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[3] Although plaintiffs' well-pleaded allegations are taken as true solely for purposes of this Rule 12(b)(6) motion, the bald assertions, unsubstantiated conclusions and unsupported characterizations set forth in the Amended Complaint are to be disregarded. See, e.g., In re Credit Suisse First Boston Corp., 431 F.3d 36, 45 (1st Cir. 2005) (affirming dismissal of Sections 10(b) and 20(a) claims); Arruda v. Sears, Roebuck & Co., 310 F.3d 13, 18 (1st Cir. 2002) (affirming dismissal); In re Segue Software, Inc. Sec. Litig., 106 F. Supp. 2d 161, 165 (D. Mass. 2000) (dismissing complaint).

[4] TYSABRI® binds to a receptor on white blood cells known as the $\alpha 4\beta 1$ human integrin receptor. (Center For Drug Evaluation And Research Medical Review at 12, App. Ex. 12 (the "Medical Review").) The $\alpha 4\beta 1$ receptor is responsible for white blood cells migrating from the blood stream into the central nervous system. (Article dated March 5, 1992, App. Ex. 10.) For this reason, it was hypothesized that TYSABRI® may be effective in treating inflammatory diseases of the central nervous system, such as MS. (Id.)

The TYSABRI® Clinical Trials

The development of any drug receives extensive FDA oversight. Once a potential drug undergoes pre-clinical animal testing, a "Sponsor" of a drug candidate (in this case, Biogen Idec) submits an Investigational New Drug Application for approval to test the candidate in humans. 21 C.F.R. § 312.20. If the request for human testing is approved, clinical trials begin and generally proceed in three phases. Phase I studies typically involve 20 to 80 volunteers, and are designed to determine the potential toxicity of the drug. Id. § 312.22(a). Phase II studies are conducted to determine the effectiveness (or efficacy) of the drug candidate for the intended indication (in this case, MS), and to monitor short term side effects. Id. § 312.22(b). Phase III studies are large trials, intended to gather additional efficacy and safety data to evaluate the overall benefit-risk relationship of the candidate. Id. § 312.22(c). Phase III results are used as the basis for the FDA's decision concerning approval.

Plaintiffs allege that Biogen Idec was primarily responsible for conducting Phase III clinical trials for MS (Am. Compl. ¶ 82), which consisted largely of two trials: (i) the AFFIRM trial, which was a two-year, placebo-controlled study involving approximately 900 patients designed to gather additional efficacy data and (ii) the SENTINEL trial, which was a two-year, placebo-controlled study involving approximately 1,200 patients designed to study the efficacy and safety of TYSABRI® in combination with another Biogen Idec MS drug, AVONEX®. (Id. ¶ 89.)

Plaintiffs allege that Elan was primarily responsible for conducting Phase III clinical trials in Crohn's (id. ¶ 82), which consisted largely of three trials: (i) ENACT-I, (ii) ENACT-II and (iii) ENCORE. (Id. ¶¶ 91-92.) Elan was also conducting Phase II trials for Rheumatoid Arthritis. (Id. ¶ 93.)

More than 5,000 patients participated in the TYSABRI® Phase III clinical trials.

The Reporting Of Safety Information In TYSABRI® Clinical Trials

To participate in the Phase III MS trials, a physician enrolled her patient and, if accepted into the trial, the physician became an "Investigator." See generally 21 C.F.R. §§ 312.50-70 (describing the obligations of drug Sponsors and Investigators). The Investigator would then administer either placebo or active drug to the enrolled patient, but because the Phase III trials were "double blinded," neither the Investigator/patient nor Biogen Idec knew whether a particular patient was receiving TYSABRI® or placebo. (Am. Compl. ¶ 89.) The Investigator is required to maintain a patient's case history, and to provide periodic reports to the Sponsor (i.e., Biogen Idec), including reports concerning safety information. 21 C.F.R. §§ 312.60-70.

The reporting requirements for safety "adverse events" during the TYSABRI® clinical trials were governed by the TYSABRI® clinical trial protocol and 21 C.F.R. § 312.32.[5] During the clinical trials, all adverse events were required to be reported by the Investigators to Biogen Idec, whether or not those events were deemed "serious" or diagnosed to be caused by (or related to) TYSABRI®. (Medical Review at 61, App. Ex. 12.)

An adverse event was classified as "serious" if it met any of the following criteria: (i) resulted in death, (ii) it was a life-threatening event, (iii) required or prolonged in-patient hospitalization, (iv) resulted in significant or persistent disability, (v) any congenital anomaly/birth defect; (vi) any other medical event that in the opinion of the Investigator required intervention to prevent any of the above from occurring and (vii) a new diagnosis of cancer. (Id. at 61.) See also 21 C.F.R. § 312.32(a)).

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[5] In the TYSABRI® clinical trials, an "adverse event" was defined as "any untoward medical occurrence experienced by a subject." (Medical Review at 60, App. Ex. 12.) "An adverse event could be any sign (including an abnormal laboratory result that the [I]nvestigator determined was clinically significant), symptom, or diagnosis/disease that was unfavorable or unintended, that appeared or worsened in a subject." (Id.)

All adverse events were reported to the FDA (regardless of the Investigator's diagnosis of seriousness or relatedness). An adverse event is required to be reported to the FDA in expedited manner (15 calendar days or 7 calendar days if the event is fatal or life threatening) if all of the following criteria are met: the event was (i) serious, (ii) unexpected and (iii) associated with the drug. 21 C.F.R. § 312.32(b). "Associated with the drug" is defined as "a reasonable possibility that the experience may have been caused by the drug." Id. § 312.32(a) (emphasis added). Accordingly, an adverse event can be both serious and unexpected, but nevertheless be diagnosed as unrelated to the drug. As demonstrated below, the Amended Complaint utterly ignores that critical (and dispositive) determination.

TYSABRI® Receives Accelerated Approval For Treatment Of MS

On February 18, 2004 (the beginning of the putative class period), Biogen Idec announced that it intended to seek accelerated approval of TYSABRI® as a treatment for MS based upon the one-year data from the Phase III MS trials.[6] (App. Ex. 1.) On May 25, 2004, Biogen Idec announced that it had submitted a Biologics License Application (the "BLA") to the FDA, and on June 28, 2004, announced that the FDA designated the TYSABRI® BLA for priority review.[7] (App. Exs. 2 and 3, respectively.)

In evaluating the data for potential approval, the FDA conducted an extensive analysis of all-then available data. (See Medical Review, App. Ex. 12.) During the review process, the FDA evaluated TYSABRI® safety data primarily from the ongoing Phase III MS

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[6] A Sponsor may apply for accelerated approval of a biological product for serious or life-threatening illnesses if the drug candidate has the potential to address an unmet medical need. See 21 C.F.R. § 601.40-51; see also Am. Compl. ¶¶ 83-85.

[7] "Priority review" means that the FDA will take action within six months, and is granted in cases where the drug candidate is "considered to be []a potentially significant therapeutic advancement[] over existing therapies that address[es] an unmet medical need. (Am. Compl. ¶ 84.)

clinical trials. (Id. at 54-55.) In addition, the FDA considered data from Crohn's clinical trials, including three then-ongoing trials. (Id. at 55.) For the ongoing studies (which included Phase III MS and Crohn's studies), the FDA evaluated "safety data through cut-off dates ranging from March 1st to April 30th, 2004." (Id.) Accordingly, the FDA determined that, in general, safety events occurring in the ongoing trials after April 30, 2004 (at the latest), would not be considered in their review for accelerated approval.

On November 23, 2004, Biogen Idec announced that the FDA approved TYSABRI® as treatment for relapsing forms of MS to reduce the frequency of relapses. (App. Ex. 4.) In granting accelerated approval of TYSABRI®, the FDA commented that TYSABRI® "has an acceptable safety profile," and "compelling evidence of efficacy." (Medical Review at 101, App. Ex. 12.)

Biogen Idec Voluntarily Suspends TYSABRI® Marketing

On February 28, 2005, Biogen Idec, in consultation with the FDA, announced the voluntary suspension of all TYSABRI® marketing, including dosing in all clinical trials. (App. Ex. 6.) The suspension was based on two serious adverse events in patients treated with TYSABRI® in combination with AVONEX® in the ongoing MS clinical trials. (Id.) The events involved one fatal, confirmed case of PML and one suspected case of PML (which would later be confirmed). (Id.) Biogen Idec also announced that it was conducting a comprehensive safety evaluation of TYSABRI®. (Id.)

On March 30, 2005, Biogen Idec announced that the comprehensive safety evaluation led to a previously diagnosed case of malignant astrocytoma being reassessed as PML in a patient participating in the Crohn's trials in 2003. (App. Ex. 7.)

On August 9, 2005, Biogen Idec announced that the comprehensive safety evaluation in patients with MS resulted in no new cases of PML, and on October 17, 2005, announced that no new cases of PML were discovered in patients with Crohn's Disease or Rheumatoid Arthritis. (App. Exs. 8 and 9, respectively.)

TYSABRI® Is Reintroduced For Treatment Of MS

The Peripheral and Central Nervous System Drugs Advisory Committee of the FDA (the "Advisory Committee") held public hearings on March 7-8, 2006, to evaluate the potential reintroduction of TYSABRI®. (Am. Compl. ¶ 356.) During those hearings, the Advisory Committee heard presentations from Biogen Idec and the FDA, and also provided sessions for public comment. (See Transcript from the Peripheral And Central Nervous System, Drugs Advisory Committee, excerpt at App. Ex. 15 ("FDA Transcript").) At the conclusion of those hearings, the Advisory Committee voted unanimously to recommend the reintroduction of TYSABRI® for the treatment of relapsing forms of MS. (Am. Compl. ¶ 356.) That recommendation was advisory only, and the FDA was not bound by it.

On June 5, 2006, the FDA approved the reintroduction of TYSABRI® as a monotherapy treatment for relapsing forms of MS. (Id. ¶ 359.) Because of the potential risk of PML, TYSABRI® is recommended for those patients who do not respond to alternative MS therapies, and then only after enrollment in a risk management plan -- TOUCH™ (TYSABRI® Outreach: Unified Commitment to Health) -- to closely monitor any signs of PML. (Id. ¶ 361.) TYSABRI® also contains a prominent warning label, warning of the increased risk of PML associated with TYSABRI® treatment. (Id. ¶ 362; see also TYSABRI® Package Insert at 1, App. Ex. 16) On July 24, 2006, TYSABRI® again became commercially available. (Am. Compl. ¶ 365.)

ARGUMENT

To state a claim for securities fraud under Section 10(b), Plaintiffs must satisfy the strict pleading requirements of Fed. R. Civ. P. 9(b) and the PSLRA. To satisfy Rule 9(b), a complaint must specify "(1) the statements that the plaintiff contends were fraudulent; (2) the identity of the speaker; (3) where and when the statements were made; [and] (4) why the statements were fraudulent." Fitzer v. Sec. Dynamics Tech., Inc., 119 F. Supp. 2d 12, 18 (D. Mass. 2000) (dismissing complaint).

In addition to Rule 9(b), a complaint alleging securities fraud must meet the statutorily heightened pleading requirements of the PSLRA. First, where -- as here -- allegations concerning material misstatements are made upon information and belief, the complaint must "state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1).[8] Second, for each allegedly false statement or material omission, a plaintiff must "state with particularity facts giving rise to a strong inference that the defendants acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2) (emphasis added). In this Circuit, this means that, at a minimum, Plaintiffs must allege particularized facts supporting a "highly likely" inference that each defendant "intended to defraud, or that [they] acted with a high degree of recklessness." Ezra Charitable Trust v. Tyco Int'l, Ltd., 466 F.3d 1, 6 (1st Cir. 2006) (affirming dismissal of fraud claims on the grounds that complaint failed to adequately allege scienter) (quotation omitted) (emphasis added).

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[8] Plaintiffs' statement that their allegations are "based upon an investigation conducted by and under the supervision of Lead Counsel for Lead Plaintiffs" (Am. Compl. ¶ 1) is equivalent to pleading on "information and belief," and does nothing whatsoever to satisfy Plaintiffs' heightened pleading burden. Carney v. Cambridge Tech. Partners, Inc., 135 F. Supp. 2d 235, 247 (D. Mass.) (2001) (holding that allegations based upon investigation of counsel must "state with particularity all facts that form the basis for the belief that fraud has occurred").

In applying these principles on a motion to dismiss, the Court should subject the complaint to a "statement-by-statement analysis in which the inquiry made is restricted to the immediate context of each statement . . . ." Carney, 135 F. Supp. 2d at 243-44. The PSLRA provides that where -- as here -- a plaintiff does not meet these pleading requirements, the complaint must be dismissed. 15 U.S.C. § 78u-4(b)(3).

I. THE SECTION 10(b) CLAIM SHOULD BE DISMISSED BECAUSE THE COMPLAINT DOES NOT STATE WITH PARTICULARITY FACTS SUPPORTING A CLAIM OF SECURITIES FRAUD

The Amended Complaint purports to identify 89 of Defendants' statements from February 18, 2004 through February 28, 2005 that Plaintiffs allege were materially false and misleading when made.[9] Plaintiffs' purported reasons why every one of those statements were known to be false and/or misleading when made fall into two broad categories: (a) Defendants "knew" that TYSABRI® would never be a widely marketable drug because it "virtually turns off the immune system" (Am. Compl. ¶ 97) and (b) Defendants failed to disclose to the FDA prior to receiving TYSABRI® approval (in November, 2004) serious adverse events reported during the clinical trials that "confirmed" TYSABRI® was a dangerous drug (id. ¶¶ 97, 129). Those conclusory reasons why statements were false and misleading are not, however, supported by particularized factual allegations. The Amended Complaint should be dismissed for this reason alone. (To assist the Court in its review of the Amended Complaint and Defendants' arguments below, attached hereto as Exhibit A is a chart identifying the alleged "supporting facts" as to why Defendants' statements were false and misleading, and summarizing the lack of particularity associated with those "facts.")

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[9] See Am. Compl. ¶¶ 164-67, 176-84, 188, 192, 195, 199-205, 209, 213-14, 216, 219-21, 223-25, 230, 232-38, 242, 244, 246, 249-52, 258-64, 268, 271-77, 280-87, 292, 295-99, 301-07, 311-15.

A. Plaintiffs' Allegations Concerning Purported Immune System Side-Effects Are Insufficient To Demonstrate That TYSABRI® Was Never Going To Be A Widely Marketable Medicine

When this case was first filed 19 months ago, the complaint claimed that putative class period statements were false and misleading because defendants "knew" that TYSABRI® "made patients susceptible to PML" and knew of "documented facts that MS drugs can cause greater incidents of PML." (Compl. ¶ 29, Docket No. 1.) Because Plaintiffs cannot support that theory, the entire premise of their case has changed.

Plaintiffs now allege that Defendants "knew" that TYSABRI® would not be a widely marketable drug because patients receiving TYSABRI® would suffer from "opportunistic infections." (Am. Compl. ¶ 97.) Plaintiffs' newfound theory, however, fails as a matter of law because TYSABRI® dosing was suspended because of the observance of PML in two patients in February 2005, not because of unidentified "opportunistic infections." (2/28/05 Press Release, App. Ex. 6.) Indeed, TYSABRI®'s "black box" label (which Plaintiffs' claim is the death knell of TYSABRI® (Am. Compl. ¶¶ 17, 360)) prominently warns of the risk of PML, not "opportunistic infections." (Am. Compl. ¶ 362; TYSABRI® Package Insert at 1, App. Ex. 16.) Accordingly, to support the theory that Defendants "knew" TYSABRI® would never be a widely marketed drug, the Amended Complaint must state with particularity facts demonstrating that Defendants knew or recklessly disregarded that TYSABRI® dosing would lead to PML (not some unidentified "opportunistic infection"). Plaintiffs do not -- and cannot -- satisfy that burden.

Plaintiffs allege that Defendants "knew" TYSABRI® would never be a marketable drug because they "knew or recklessly disregarded" (i) that TYSABRI® was unacceptably dangerous because it "virtually 'turns off' the immune system," leaving patients defenseless against infections (Am. Compl. ¶ 67), (ii) "warnings" in selected scientific publications and conferences concerning potential immunosuppressive effects of TYSABRI® (id. ¶ 97) and (iii)

results from the TYSABRI® clinical trials which "confirm" that TYSABRI® "effectively turns off [the] immune system" (id. ¶ 152). None of those allegations, however, are supported by particularized facts, nor are they sufficient to establish that Defendants knew TYSABRI® would lead to PML. To the contrary, those allegations are contradicted by the very documents on which Plaintiffs purport to rely.

1. Plaintiffs' Contention That TYSABRI® "Turns Off" The Immune System And Is Therefore Unacceptably Dangerous Is Not Supported By Particularized Facts

Plaintiffs' erroneous allegation that TYSABRI® "turns off" the immune system is predicated almost entirely upon assertions of alleged conclusions that Plaintiffs attribute to Dr. Lawrence Steinman. (Id. ¶¶ 64-67, 98-100, 104.) Dr. Steinman, however, did not make any of the sweeping conclusions that Plaintiffs attribute to him, nor did he (or anyone else) ever express any concerns about PML.

Plaintiffs allege that -- in an article published on March 5, 1992 -- Dr. Steinman concluded that TYSABRI® "turns off" the immune system because it "prevent[s] white blood cells from migrating to ***all*** organs in the body." (Id. ¶¶ 65-66 (emphasis in original).) That article, however, made no such conclusions. (See App. Ex. 10.) To the contrary, that preliminary research led to the hypothesis that the precursor to TYSABRI® "prevented the accumulation of [white blood cells] in the central nervous system . . . . and may be useful in treating inflammatory diseases of the central nervous system, such as multiple sclerosis." (Id. at 63.) There was simply no discussion of any concerns that TYSABRI® would leave "patients that developed infections in other organs [] defenseless to fight the infection." (Am. Compl. ¶ 64.)

Dr. Steinman's subsequent 2004 "concerns" cited by Plaintiffs also refute the notion that he concluded that TYSABRI® "turns off" the immune system. (Id. ¶ 106.) In that 2004 article, Dr. Steinman stated that although TYSABRI® (or α4-integrin) was selective in its action, it was not, in his view, selective enough because it potentially blocked certain immune system cells from entering the intestine, as well as the central nervous system. (Article dated July 9, 2004 at 213-14, App. Ex. 11.) Indeed, Dr. Steinman wrote that then-current therapies, including TYSABRI®, had not "shown the level of exquisite specificity originally envisioned." (Id. at 213 (emphasis added).) That is in stark contrast to Plaintiffs' assertions that TYSABRI® "turns off" the entire immune system.[10] (Am. Compl. ¶¶ 67, 97.)

Plaintiffs also allege that Dr. Steinman was purportedly concerned about "'horrendous infectious diseases'" such as "atypical pneumonias, tuberculosis and brain abscesses." (Id. ¶ 105.) As an initial matter, Plaintiffs do not allege that Dr. Steinman expressed any of those purported concerns to any Defendant, or when he had those alleged concerns. Further, conspicuously absent from any of those concerns is PML. (Id.) Simply put, there was nothing that warned Defendants of a risk of PML associated with TYSABRI®.

Lastly, the FDA had access to Dr. Steinman's "conclusions," but nevertheless granted accelerated approval of TYSABRI® as a treatment for MS. (11/23/04 Press Release, App. Ex. 4.) Plaintiffs' allegations are nothing more than impermissible "fraud by hindsight."

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[10] Plaintiffs also reference animal studies that they claim support their assertion that TYSABRI® "turns off" the immune system. (Am. Compl. ¶¶ 101, 103.) Those allegations, however, are so conclusory and non-specific that their inclusion only serves to highlight the Amended Complaint's gross lack of particularity. (Id. ¶ 103.) Plaintiffs conclusorily assert that "unexplained deaths" of very few animals demonstrates that TYSABRI® was "highly immunosuppressive," but unsurprisingly offer no supporting facts for that conclusion. (Id.) Indeed, Plaintiffs offer no more than speculation and innuendo as to the cause of those alleged deaths -- let alone any conclusions to be drawn from them. That is simply insufficient.

2. Plaintiffs' Allegations Concerning Discussions Of *Theoretical* TYSABRI® Side-Effects Are Insufficient To Demonstrate "Fraud"

Plaintiffs' allegations that Defendants "knew or should have known" that patients would suffer from PML based upon a selection of published articles and scientific conferences is not even remotely supported by particularized factual allegations. (Am. Compl. ¶¶ 106, 108-118.)

First, those "warnings" do not even mention the possibility of PML; rather they suggest only a "theoretical concern that recipients of the therapy would become generally compromised in their ability to fight infection," a conclusion likely when using any type of immunomodulating drug, of which TYSABRI® is one of many. (Id. ¶ 106 (emphasis added).)[11] Those academic hypotheticals, however, fall far short of pleading with particularity facts demonstrating that each Defendant knew that the statements identified in the Amended Complaint were false and misleading when made. Orton v. Parametric Tech. Corp., 344 F. Supp. 2d 290, 299 (D. Mass. 2004) (holding that plaintiffs must set forth "specific facts" that make it "reasonable to believe that the defendant knew a statement was materially false or misleading") (emphasis added).

Second, even if those theoretical discussions were sufficient to raise concerns about potential risks of PML in patients treated with TYSABRI® -- and they plainly are not -- the Amended Complaint does not establish what any Defendant knew, or when they knew it. For example, Plaintiffs allege that "Dr. Miller . . . recommended to senior Biogen officials that they should conduct additional animal studies," but nowhere does the Amended Complaint allege

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[11] At most, Plaintiffs' citation to certain studies indicates that more tests and observations are desirable, not that TYSABRI® will never be a widely marketed drug or an effective treatment for MS as Plaintiffs would have it. (See, e.g., Am. Compl. ¶ 108 ("[f]urther studies will be required to determine the longer effect of this treatment" (brackets in original)); ¶ 110 ("Continued examination . . . will be required").

with particularity which Defendant (if any) Dr. Miller purportedly raised his concerns with, when this discussion occurred or what was said. (Am. Compl ¶ 118.)

Plaintiffs' allegation that Dr. Steinman "made strong warnings" about TYSABRI® at two conferences in 2004 and 2005 similarly fall flat. (Id. ¶ 118.) Plaintiffs do not particularize what was allegedly said at those conferences, or which Defendant (if any) participated in such discussions. Indeed, Plaintiffs do not provide any specific details at all about those purported conferences (or who even attended them).

3. The Results From The Clinical Trials Refute (Rather Than Support) Plaintiffs' Claim That TYSABRI® "Turns Off" The Immune System

Plaintiffs allege that adverse event report data they claim to have obtained through a FOIA request "confirms" that TYSABRI® "turns off" the immune system. (Id. ¶ 152.) In support of that position, Plaintiffs insert a grossly misleading chart of infections that Plaintiffs allege were observed during the TYSABRI® clinical trials from November 24, 2004 through March, 2006. (Id. ¶ 153.) But the purported data in that chart, along with the other allegations in that section of the Amended Complaint (id. ¶¶ 152-161), are general and non-specific, and also are conclusively rebutted by the publicly disclosed results from the clinical trials.

Plaintiffs erroneously allege that "at least sixty opportunistic infections" were observed during the TYSABRI® clinical trials. (Id. ¶ 153.) As reported during the Advisory Committee hearings, however, only 8 "opportunistic infections" were observed during all of the clinical trials (3 in the MS trials and 5 in the Crohn's trials) -- not 60. (FDA Trans. 62:8-19, 63:3-8, App. Ex. 15.) To reach 60 infections, Plaintiffs simply count the same adverse event multiple times, likely because a new adverse event report is generated every time a patient has a follow-up visit for a single event. (Plaintiffs could have eliminated this multiple counting had they merely compared the patient numbers on the reports they claim to have received.) For

example, Plaintiffs claim that there were 11 cases of meningitis herpes and 5 cases of encephalitis herpes (Am. Compl. ¶ 153), when in truth there was only 1 case of each (for a total of 2, not 16).[12] Also contributing to Plaintiffs' inflated number is the listing of infections that are not even considered opportunistic -- including, but not limited to, sepsis, herpes, gangrene, pyelonephritis, escherichia sepsis and septic shock. (Id.) Lastly, Plaintiffs do not allege if the infections listed were even diagnosed as caused by (or related to) TYSABRI® dosing. Even if "60 opportunistic infections" were observed during the clinical trials -- and they were demonstrably not -- the lack of any particularized allegations concerning whether TYSABRI® caused those infections renders Plaintiffs' chart irrelevant.[13]

Plaintiffs' allegations of purported malignancies also are insufficient to demonstrate that TYSABRI® "turns off" the immune system. (Id. ¶ 155.) Plaintiffs do not allege that any of those malignancies were diagnosed as caused by (or related to) TYSABRI® and, indeed, they do not even allege that they occurred in patients taking TYSABRI® (as opposed to the patients in the placebo group). Plaintiffs' failure is not surprising -- during the clinical trials the placebo group experienced more malignancies (nearly double) than TYSABRI®-treated patients. (FDA Trans. 51:9-11, App. Ex. 15 ("1.3 percent of placebo-treated patients had a malignancy versus 0.7 percent of those on [TYSABRI®]").)

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[12] During the Advisory Committee hearings, Biogen Idec presented those 2 (not 16) herpes cases. (FDA Trans. 57:1-8, App. Ex. 15.) (See also TYSABRI® Package Insert at 14, App. Ex. 16 (describing those two herpes' cases).) Plaintiffs multiple counting is further demonstrated by separate entries for PML and JC Virus Infection -- there were a total of three, not five. (Am. Compl. ¶ 153.)

[13] Plaintiffs' chart at ¶ 154 is similarly vague and non-particular. Listing events such as "diarrhea," "infection," "respiratory tract infection," "oral infection" and "eye infection" is meaningless. (Am. Compl. ¶ 154.) Further, Plaintiffs again do not say if those "infections" were even diagnosed as related to TYSABRI®.

Lastly, Plaintiffs' speculation and hyperbole concerning the misdiagnosis of the PML patient in the Crohn's trial do not support a claim of fraud. (Am. Compl. ¶¶ 156-58.) Plaintiffs identify two "confidential sources" that purport to state that the misdiagnosis was "highly suspicious," and recklessly assert that it was either an "effort to conceal the true diagnosis or malpractice." (Id. ¶¶ 156-57.) Those theories and opinions notwithstanding, none of those "confidential sources" claim to have reviewed that patient's files, spoken with any Defendant, or purport to know what any Defendant in this case knew and when they knew it. Simply put, those allegations cannot support Plaintiffs' claims of fraud.

B. Plaintiffs' Allegation That Defendants Did Not Disclose Serious Adverse Events To The FDA Is Conclusory, And Contradicted By The Documents Incorporated Into The Complaint

Plaintiffs' second theory as to why the 89 statements identified in the Amended Complaint were false and misleading concerns allegations that, prior to receiving approval for TYSABRI® based upon one-year data from the MS trials, Defendants did not disclose to the FDA "serious opportunistic infections" that purportedly occurred up to that point during the MS and Crohn's clinical trials (Id. ¶ 129.) In support of that conclusion, Plaintiffs claim that they conducted an "exhaustive search of the FDA website" and found that "Defendants specifically concealed 'opportunistic' infections that occurred during the TYSABRI® clinical trials." (Id.) That allegation, however, is not supported by particularized facts and, indeed, is contradicted by the very documents Plaintiffs purport to have uncovered during their "exhaustive search." (Id.)

Plaintiffs base their failure to disclose theory upon an incomplete quotation from a single document (out of hundreds) submitted in connection with the TYSABRI® licensing application for accelerated approval:

> The events reported do not appear to represent infections due to opportunistic pathogens; however, given the mechanism of action of [TYSABRI®], this issue deserves continued scrutiny, both via post-marketing surveillance and via post-marketing commitments agree to by [Biogen Idec] to more fully characterize the effect of [TYSABRI®] on the immune system.

(11/23/04 Memorandum from David Ross at 9, App. Ex. 13 (the "Ross Memo") (emphasis added); Am. Compl. ¶ 130).) Plaintiffs interpret the emphasized portion of that sentence to mean that Defendants did not report any so-called "opportunistic infections" to the FDA when seeking accelerated approval (Am. Compl. ¶ 130), and then devote the next twenty paragraphs of the Amended Complaint in hopes of demonstrating that Defendants knew that certain serious adverse events were caused by "opportunistic infections." (Id. ¶¶ 132-151.) Not only do those allegations fail to provide particularized support for Plaintiffs' contention that Biogen Idec concealed results from the FDA, but they actually contradict it.

As an initial matter, Plaintiffs misconstrue what adverse event data the FDA considered during the TYSABRI® accelerated approval process (which is crucial since the only allegation Plaintiffs rely upon is the incomplete quotation from the Ross Memo commenting on that data). During the review, the FDA made a determination that it would consider safety data only through April 30, 2004, at the latest. (Medical Review at 55, App. Ex. 12.) Accordingly, the Ross Memo did not comment on adverse events that occurred in any clinical trial after April 30, 2004. As demonstrated below, that alone defeats Plaintiffs' failure to disclose theory.

First, Plaintiffs mischaracterize the results presented by Biogen Idec (and the FDA) during the Advisory Committee hearings in March, 2006. (Id. ¶¶ 132-140.) Plaintiffs allege that Biogen Idec observed a "substantial number of opportunistic infections" during the clinical trials (id. ¶ 126), when in fact only 8 patients (out of 3,900, or 0.2%) in both the MS and Crohn's clinical trials experienced infections categorized as opportunistic (3 patients in the MS

trials, and 5 patients in the Crohn's trials). Plaintiffs provide no details as to when those events occurred, which clinical trials they occurred in or what was the causality diagnosis (i.e., was the event diagnosed as related to TYSABRI® infusions). Indeed, Plaintiffs do not provide any particularized details of those adverse events at all.

Second, Plaintiffs purport to rely on five "confidential sources" to demonstrate that Defendants "knew" that opportunistic infections occurred during the clinical trials. (Id. ¶¶ 143-151.) The allegations attributed to those "confidential sources," however, are so lacking in particulars and specificity that they do not -- and cannot -- support a claim of securities fraud. Notably, not one of those "sources" alleges that Defendants failed to disclose any serious adverse event data to the FDA (and they could not in good faith so allege).

Third, the large majority of what Plaintiffs deem to be opportunistic infections occurred in the Crohn's trials -- which Plaintiffs allege were managed and controlled by Elan. (Id. ¶ 82.) In an effort to impute particulars of alleged adverse events in the Crohn's trials to any Defendant in this case, Plaintiffs conclusorily state that by virtue of the Collaboration Agreement, Biogen Idec and Elan were required to communicate regularly, therefore Defendants must have known of those particulars. (Id. ¶¶ 141-42.) While it is certainly true that Biogen Idec and Elan communicated regularly, Plaintiffs must allege with particularly what information was contained in those adverse events, when those adverse events were reported to Elan, when those adverse events were reported to Biogen Idec and what was reported to Biogen Idec. Plaintiffs' *must-have-known* allegation is insufficient as a matter of law.

Fourth, Plaintiffs' allegations that Defendants knew of the two PML events that led to the voluntary suspension prior to receiving TYSABRI® approval are not supported by any particularized factual allegations. (Id. ¶¶ 318-22.) At most, Plaintiffs' allegations amount to a hindsight criticism of those patients' doctors for not diagnosing PML earlier in time. Indeed,

those allegations are silent as to when those events were even reported to Biogen Idec, what the original diagnoses were or what the original causality assessments were. (Id.)

1. Plaintiffs' Allegations Concerning The Advisory Committee Presentations Do Not Support (And, Indeed, Contradict) Plaintiffs' Failure To Disclose Theory

Plaintiffs allege that Defendants "admitted" during the March 2006 Advisory Committee hearings that they "were aware of numerous opportunistic infections that occurred during the TYSABRI® clinical trials, prior to FDA approval, which were not previously disclosed to the FDA." (Id. ¶ 132.) Defendants, of course, made no such admission.

Almost completely lacking from Plaintiffs' allegations are any particulars as to when the adverse events identified in the Amended Complaint (and discussed during the hearings) actually occurred, and also whether those events were diagnosed as related to TYSABRI® infusions. (Id. ¶¶ 133-40.) Those omissions are dispositive of Plaintiffs' failure to disclose theory because Plaintiffs rely exclusively on the Ross Memo (id. ¶¶ 129-30), which discusses only events that were caused by TYSABRI® infusions, and limits that discussion to safety data gathered through April 30, 2004 (at the latest), when several MS and Crohn's clinical trials were still then-ongoing (Medical Review at 55, App. Ex. 12).

Further, Plaintiffs allege that "***seventeen deaths***" occurred during the clinical trials, "***thirteen of which were in patients taking Tysabri***" (Am. Compl. ¶ 133 (emphasis in original)), but do not allege when those deaths occurred or what was the cause of death.[14] Those

[14] For example, among the deaths reported was a work related accident attributed to "carbon monoxide poisoning." (Medical Review at 55, App. Ex. 12.) Plaintiffs wish to create a taint by alleging "seventeen deaths," but never acknowledge that those deaths were not attributed to TYSABRI® at the time. Indeed, the Medical Review discusses each death that had occurred during the clinical trials up to April 30, 2004 (9 total and 6 in TYSABRI®-treated patients), making it clear that at least three of those deaths were completely unrelated to TYSABRI®. (Id.)

details are, of course, crucial to the survival of a suit alleging securities fraud, but entirely (albeit understandably) missing from the Amended Complaint.[15]

In addition to the dispositive failure of providing any dates or causality assessments, Plaintiffs also mischaracterize the data presented during the Advisory Committee hearings. While Plaintiffs claim that "numerous opportunistic infections" occurred during the clinical trials, in truth there were only 8 opportunistic infections observed during all of the clinical trials.[16] During the hearings, Dr. Michael Panzara (Director of Medical Research at Biogen Idec) presented safety data from the MS and Crohn's trials, which amounted to a total of approximately 3,900 patients that received TYSABRI® infusions. (See FDA Transcript at 49-50, App. Ex. 15 (stating that 2,300 MS patients and 1,600 Crohn's patients received TYSABRI®).) Only 3 patients in the MS clinical trials developed opportunistic infections, and two of those patients were the PML patients that resulted in the voluntary suspension of TYSABRI®. (Id. at 62:8-19.) During the Crohn's trials, 5 patients were diagnosed as having suffered from an opportunistic infection. (Id. at 63:3-8.) Accordingly, only 8 patients (out of approximately 3,900) experienced "opportunistic infections," or an incidence of 0.2%.

Lastly, Plaintiffs' contention that Defendants "specifically concealed 'opportunistic' infections . . . from the FDA" is flatly contradicted by the FDA Hearing transcript,

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[15] Plaintiffs refer to, among other things, the deaths of the PML patients (Am. Compl. ¶ 133), but also concede that those deaths occurred long *after* Defendants sought accelerated approval. (Id. ¶ 324.) Similarly, Plaintiffs' allegations of two cases of herpes infections occurring in February 2005 are irrelevant to experiences observed during the clinical trials through April 30, 2004 -- the only adverse events the Ross Memo commented upon. (Id. ¶ 137.)

[16] Plaintiffs mistakenly label, among other things, "herpes virus infections" and "lower respiratory tract infections" as opportunistic (Am. Compl. ¶ 134), but neither Biogen Idec nor the FDA categorized those infections in that manner. (See FDA Trans. at 54-55, 161-62, App. Ex. 15) (discussing opportunistic infections separate from herpes and lower respiratory tract infections).

and the FDA Medical Review. (Am. Compl. ¶ 129.) During the Hearings, Dr. Panzara presented a death in the Crohn's trials from pulmonary aspergillosis -- an opportunistic infection. (FDA Trans. 53:5-12, 63:19-22, App. Ex. 15.) The FDA Medical Review discusses all deaths that occurred during the TYSABRI® clinical trials up to April 30, 2004, and specifically refers to a death in the Crohn's trials due to "pulmonary aspergillosis." (Medical Review at 55, App. Ex. 12.) In short, Defendants did disclose any opportunistic infections to the FDA; Plaintiffs' claims to the contrary are demonstrably false.

2. The Generalized Allegations Attributed To "Confidential Sources" Do Not Support Plaintiffs' Failure To Disclose Theory

Plaintiffs purport to identify five "confidential sources" in this section of the Amended Complaint (Am. Compl. ¶¶ 143-51), and claim that those sources "confirm that Defendants knew of the serious opportunistic infections that occurred during the Tysabri clinical trials." (Id. ¶ 144.) The allegations attributed to those "confidential sources," however, do not support that Defendants failed to disclose safety data to the FDA, and also are not sufficiently particular to establish which Defendant allegedly knew what information and when. (See id. ¶¶ 143-151.)

At most, the "confidential sources" claim -- albeit generally -- that a few opportunistic infections occurred during the TYSABRI® clinical trials (mostly in the Crohn's trials). (Id. ¶¶ 144-50.) Importantly, none of those "confidential sources" claim that any Defendant failed to disclose any safety data to the FDA. Instead, the Amended Complaint states that certain "confidential sources" recalled a few purported examples of opportunistic infections, but then conclusorily alleges "[n]one of these opportunistic infections, however, were disclosed to the FDA . . . ." (Id. ¶¶ 144, 145, 147.) That conclusion, however, is not attributed to any "source." That alone is dispositive of those allegations.

Further, the allegations attributed to the confidential sources are not particular. For example, "confidential source No. 6," who is described as a "Data Entry Clerk," claims that he or she was "certain that Defendants were aware of any concerns relating to the Tysabri clinical trials." (Id. ¶¶ 148-49.) That "confidential source," however, does not describe any conversation with any Defendant, or any data presented to any Defendant and when that data was presented. In addition, that "confidential source" claims that a "large volume of adverse events associated with Tysabri were being reported to Biogen – on average, between fifty and sixty adverse events were reported daily." (Id. ¶ 148.) But lacking from those allegations are necessary details such as were those reports from patients taking TYSABRI® or placebo, were those adverse events deemed serious, and were those events categorized as related to TYSABRI® infusions. (Of course, a data entry clerk, who may have no medical training at all, would not be competent to put forth allegations as to those issues.)

The allegations attributed to the remaining "confidential sources" are similarly vague and conclusory. None of those confidential sources state when any serious adverse event occurred, which Defendant (if any) knew of such adverse events or whether those adverse events were diagnosed as caused by TYSABRI®. Instead, those "confidential sources" conclusorily claim that "Biogen had access to the data" and there was a "concern at Biogen that Tysabri might leave people unable to deal with other infections," and there were "concerns in the Company about the fast-tracking of Tysabri." (Id. ¶¶ 145, 150.) Conspicuously absent from those allegations are necessary particulars such as what data was accessible, when was that data gathered, who had those vague "concerns" and how do the "confidential sources" know about the "concerns" of any Defendant. Those allegations fall far short of demonstrating fraud. In re Vertex Pharm., Inc. Sec. Litig., 357 F. Supp. 2d 343, 354 (D. Mass. 2005) (dismissing complaint

and finding allegations attributed to confidential sources inadequate where those allegations lacked "specific dates" and contained "very vague" descriptions of events).

3. Allegations That Defendants *Must Have Known* Of Safety Data In The Crohn's Trials Fail As A Matter Of Law

Almost all of the adverse event data that is generally described in the Amended Complaint is alleged to have occurred in the Crohn's trials, not the MS trials. (Am. Compl. ¶¶ 134, 144, 145, 147.) Indeed, other than the two PML cases in February, 2005, only one opportunistic infection (cryptosporidial gastroenteritis) was observed in all of the MS clinical trials. (See Am. Compl. ¶ 144; FDA Trans. at 62:8-17, App. Ex. 15; TYSABRI® Package Insert at 14, App. Ex. 16.) Even if Plaintiffs had sufficiently alleged that any safety data from the Crohn's trials was withheld from the FDA -- and they have not -- Plaintiffs' allegations nevertheless fail because Plaintiffs have not adequately alleged the particulars of any adverse event reported during the Crohn's trials.

There is not a single allegation in the Amended Complaint that describes with particularity what adverse event data was received by Elan, when it was received, what was shared with Biogen Idec and when it was shared. Instead, Plaintiffs merely purport to describe the obligations of Biogen Idec and Elan pursuant to the Collaboration Agreement and conclude "information and results learned by Biogen or Elan concerning positive or negative results of the drug was shared," and Defendants "*would have known* about serious opportunistic infections that occurred in any of the Tysabri clinical trials by virtue of their duties under the Collaboration Agreement and their positions at Biogen."[17] (Am. Compl. ¶¶ 70, 142 (emphasis added).) Courts

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[17] Similarly deficient are Plaintiffs' citations to yet another "confidential source" who purports to state that "Biogen joined forces with Elan to capitalize on the development of Tysabri" and "Biogen and Elan created a committee comprised primarily of senior management from both companies to monitor the progress of Tysabri." (Am. Compl. ¶¶ 69, 71.) That

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in this Circuit routinely reject such boilerplate and conclusory allegations of knowledge. Maldonado v. Dominguez, 137 F.3d 1, 9-10 (1st Cir. 1998) (rejecting allegations that defendants must have been aware of facts by virtue of their positions); Orton, 344 F. Supp. 2d at 306 (rejecting "vague assertion[s] that a defendant must have known about the fraud by virtue of his position of authority"); Carney, 135 F. Supp. 2d at 255 ("status" and "general allusions to unspecified corporate information" insufficient to plead knowledge).

4. Plaintiffs' Conclusory Allegations That Defendants Failed To Timely Report The PML Adverse Events Do Not Support A Claim Of Fraud

Plaintiffs also allege -- in the same conclusory fashion -- that "an internal memorandum" from Biogen Idec to treating physicians demonstrates that Defendants "knew" of the two PML adverse events that occurred in the MS clinical trials before February 18, 2005. (Am. Compl. ¶ 318; see also 2/28/05 Letter, App. Ex. 14 (the "Memorandum").) Plaintiffs allege that the Memorandum states that the PML patients "showed neurological problems as early as November 2004" as a result of PML. (Am. Compl. ¶¶ 319-20.) Lastly, Plaintiffs allege that during the Advisory Committee hearings, Defendants acknowledged that the two PML patients "began experiencing PML symptoms in October and November 2004," but "concealed these serious adverse events from the public and the FDA." (Id. ¶ 322.)

Missing from Plaintiffs' allegations are any particularized facts of when the physicians of the PML patients reported any adverse events to Biogen Idec, when any Defendant became aware of any adverse events concerning those patients, what those adverse events (if any) consisted of, what were the original diagnoses of the treating physicians and what was the causality assessment of any adverse event. Indeed, Plaintiffs allege that PML was a potential

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"confidential source" does not say who was on such a committee, what information was presented at any committee meeting or when. Yet again, that "confidential source" adds absolutely nothing of any moment to a charge of securities fraud.

diagnosis of one of the patients on February 12, 2005, but there are no allegations of when that potential diagnosis was communicated to Defendants. (Id. ¶ 319.) At most, Plaintiffs' allegations amount to unjustified after-the-fact criticisms of those patients' treating physicians. Those hindsight critiques, however, are insufficient to support a claim of securities fraud against any defendant in this case.

II. THE SECTION 10(b) CLAIM FAILS FOR THE INDEPENDENT REASON THAT THE COMPLAINT DOES NOT RAISE A *STRONG* INFERENCE OF SCIENTER

The Section 10(b) claim should be dismissed for the independent reason that Plaintiffs fail to "state with particularity facts giving rise to a strong inference that [Defendants] acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). As discussed in detail above, the Amended Complaint fails to allege with particularity that each Defendant knew or recklessly disregarded purported "warnings and red flags" concerning any risk of PML associated with TYSABRI®. (Am. Compl. ¶ 381-83.) In addition to that dispositive failure, Plaintiffs "motive and opportunity" allegations also fail to raise a strong inference of scienter. (Id. ¶¶ 384-407.)

A. Allegations Of Stock Sales Fail To Raise A Strong Inference Of Scienter

Plaintiffs allege that scienter is demonstrated by the stock sales of Dr. Rastetter, Mr. Mullen, Dr. Adelman and Mr. Rohn during the putative class period.[18] (Am. Compl. ¶¶ 385-96.) To raise the requisite strong inference of scienter, however, Plaintiffs must allege with particularity that those stock sales were either unusual or suspicious in timing or amount. Greebel, 194 F.3d 185, 197 (1st Cir. 1999). Scienter allegations, such as those allegations of

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[18] Plaintiffs also include the alleged stock trading of Mr. Bucknum, but "Plaintiffs bring a claim against Defendant Bucknum solely pursuant to Section 20A of the Exchange Act." (Am. Compl. ¶ 38.) Accordingly, Mr. Bucknum's alleged trading is irrelevant to Plaintiffs' scienter allegations. Further, there are no allegations that Mr. Kellogg traded Biogen Idec securities during the putative class period and, consequently, there is not even a scintilla of any inference of scienter as to him.

stock sales here, "do not pass the 'strong inference' test when, viewed in light of the complaint as a whole, there are legitimate explanations for the behavior that are equally convincing." Ezra, 466 F.3d at 6.

In this case, Plaintiffs allege that the "Individual Defendants' stock sales were strategically timed to coincide with key events." (Am. Compl. ¶ 394). Conspicuously absent from Plaintiffs' allegations, however, is any reference to the publicly disclosed fact that a substantial majority of the trades identified in the Amended Complaint were made pursuant to stock trading plans adopted under SEC Rule 10b5-1 (17 C.F.R. § 240.10b5-1) (see Form 4s at App. Exs. 17-20):

Defendant	Total Number Of Shares Sold During Putative Class Period	Total Number Of Shares Sold Pursuant To 10b5-1 Plan	Percentage Sold Pursuant To 10b5-1 Plan
Dr. Rastetter	175,934[19]	120,313	69%
Mr. Mullen	187,500[20]	186,500	99.5%
Dr. Adelman	80,870	70, 870	87.6%
Mr. Rohn	350,000	270,800	77.4%

[19] Plaintiffs inaccurately list Dr. Rastetter's stock sales. (Am. Compl. ¶ 387.) As an initial matter, the stock "sale" of 277,651 shares on May 14, 2004 were not sold, but in fact transferred to Dr. Rastetter's ex-wife pursuant to a domestic relations order. (See 5/18/04 Form 4, App. Ex. 17.) Dr. Rastetter therefore did not receive $16,242,584 in proceeds from this transfer of ownership. (Am. Compl. ¶ 387.) In addition, after a diligent search, Defendants were unable to locate a record for Dr. Rastetter's purported sale of 130,000 shares on May 17, 2004.

[20] Plaintiffs' allegations of Mr. Mullen's stock sales are also inaccurate. (Am. Compl. ¶ 388.) According to the Form 4s filed with SEC, Mr. Mullen sold 187,500 shares, not 192,000 as alleged. (See App. Ex. 18.)

Stock trades by insiders initiated pursuant to Rule 10b5-1 plans "raise an inference that the sales were pre-scheduled and not suspicious." Wietschner v. Monterey Pasta Co., 294 F. Supp. 2d 1102, 1116-17 (N.D. Cal. 2003) (emphasis added).

The stock sales attributed to Mr. Rohn fail to raise a strong inference of scienter for the independent reason that Mr. Rohn announced his retirement from Biogen Idec during the putative class period. (App. Ex. 5.) Stock trading by an executive preparing to retire is not suspicious or unusual, and fails to raise a strong inference of scienter. See Greebel, 194 F.3d at 206 (sales by retiring individual, which constituted a vast majority of sales alleged in complaint, not suspicious because individual was leaving the company).

B. Bare Allegations Of "Motives" To Receive Bonus Compensation Or Increase Profits Are Insufficient To Raise A Strong Inference Of Scienter

Plaintiffs also allege that the individually named defendants were "motivated" to commit fraud in order to (i) "maximize their annual bonuses" (Am. Compl. ¶ 397), avoid (ii) "los[ing] a substantial portion of Avonex® sales to Tysabri," (id. ¶ 402) and (iii) maximize TYSABRI® sales (id. ¶ 406).

Allegations of motives to increase a defendant's compensation package or enhance a company's business prospects have been uniformly rejected as insufficient to raise a strong inference of scienter. Ezra Charitable Trust v. Tyco Int'l, Ltd., No. 02-MDL-1353-PB, Civ. 03-CV-1355-PB, 2005 WL 2127619, at *4 (D.N.H. Sept. 2, 2005) (dismissing complaint and holding that defendants sought to make misstatement in order to receive substantial salaries and bonuses insufficient to raise strong inference of scienter), aff'd, 466 F.3d 1 (1st Cir. 2006); In re Eaton Vance Corp. Sec. Litig., 206 F. Supp. 2d 142, 154 (D. Mass. 2002) (dismissing complaint and holding that plaintiffs' allegations of motive based on general financial incentives insufficient to raise a strong inference of scienter). See also Greebel, 194 F.3d at 197 ("catch-all

allegations that defendants stood to benefit from wrongdoing . . . are [not] sufficient" (citation omitted)); In re Stone & Webster Sec. Litig., 414 F.3d 187, 215 (1st Cir. 2005) (finding insufficient profit motive allegations of concealment by auditor to protect business relationship and source of consulting and auditing fees).

III. DEFENDANTS' FORWARD-LOOKING STATEMENTS OF FUTURE EARNINGS AND POTENTIAL TYSABRI® MARKET SIZE ARE PROTECTED BY THE MULTIPLE SAFE HARBOR PROVISIONS OF THE PSLRA

Under the multiple "safe harbor" provisions of the PSLRA, a forward-looking statement, whether written or oral, is non-actionable if (i) it is identified as forward-looking and is "accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement" or (ii) it is "immaterial" or (iii) plaintiff does not plead that the statement was made "with actual knowledge . . . that the statement was false or misleading." 15 U.S.C. § 78u-5(c)(1)(A)-(B).[21]

A. Forward-Looking Statements Accompanied By Cautionary Language Are Protected By The PSLRA's Safe Harbor Provisions

The first safe harbor (see 15 U.S.C. § 78u-5(c)(1)(A)(i)) provides dispositive protection for all of the forward-looking statements identified in the Amended Complaint. Once the Court determines that the statements challenged in Biogen Idec's press releases and conference call transcripts were identified as forward-looking and contained meaningful cautionary language, the inquiry as to those statements ends because they are consequently non-

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[21] The PSLRA defines forward-looking statements to include (i) projections of revenue, income, or earnings, (ii) management's plans and objectives, (iii) statements of future economic performance and (iv) statements concerning the assumptions underlying the foregoing. 15 U.S.C. § 78u-5(i)(1). Defendants' statements of revenue and market projections (see Am. Compl. ¶¶ 176, 178-79, 183, 200-02, 233, 236-37, 268, 299, 301-04), as well as statements of goals and plans for TYSABRI® (see id. ¶¶ 180-81, 184, 203, 213, 219, 234-35, 237, 246, 251, 260, 272, 280, 283-84, 295-96) plainly fall within that definition.

actionable as a matter of law. See Baron v. Smith, 380 F.3d 49, 53-54 (1st Cir. 2004) (affirming dismissal and holding that forward-looking statements in press release were protected by statutory safe harbor); Meyer v. Biopure Corp., 221 F. Supp. 2d 195, 204 (D. Mass. 2002) (dismissing complaint on the grounds that identified statements were forward-looking and cautionary language "identifie[d] the risks at issue in the complaint"). In addition, if a forward-looking statement is "accompanied by 'meaningful cautionary language,' the defendants' state of mind is irrelevant." Harris v. Ivax Corp., 182 F.3d 799, 803 (11th Cir. 1999) (affirming dismissal on the grounds that forward-looking statements were protected by the PSLRA's safe harbor provisions) (emphasis added).

Every one of the press releases identified in the Amended Complaint contain express warnings that forward-looking statements identified therein were subject to change and other certain risk factors, and included specific additional disclosures concerning where investors could obtain further information concerning the risk factors that might impact its future prospects.[22]

B. The Forward-Looking Statements Are Non-Actionable Under The Independent "Known Falsity" Safe Harbor

Separate and apart from the first safe harbor, the PSLRA establishes a second, independent (and equally dispositive) safe harbor that precludes liability for any forward-looking

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[22] See, e.g., 2/18/04 Press Release, App. Ex. 1 ("Factors which could cause actual results to differ materially from the companies' current expectations include the risk that unexpected concerns may arise from additional data or analysis or that regulatory authorities may require additional information or further studies or that the companies may encounter other unexpected hurdles. For more detailed information on the risks and uncertainties associated with the companies' drug development and other activities, see the periodic reports of IDEC Pharmaceuticals Company, Biogen, Inc. and Elan Corporation, plc filed with the Securities and Exchange Commission.").

statement -- even if not identified as such -- unless the maker of the statement had "actual knowledge it was false or misleading." Carney, 135 F. Supp. 2d at 245 (citation omitted).

All of the forward-looking statements are non-actionable because Plaintiffs have not alleged facts giving rise to a strong inference that Defendants had actual knowledge of their falsity. In re Ibis Tech. Sec. Litig., 422 F. Supp. 2d 294, 310-11 (D. Mass. 2006) (dismissing forward looking statements and holding that plaintiffs must plead actual knowledge of falsity with particularity, and recklessness is not sufficient); Parametric Tech., 300 F. Supp. 2d at 219 (holding that forward-looking statements are protected by the PSLRA's safe harbor provisions "'unless the maker of the statement had actual knowledge it was false or misleading'") (quoting Greebel, 194 F.3d at 201).

IV. PLAINTIFFS' CONTROL PERSON ALLEGATIONS FAIL TO STATE A CLAIM

Without a viable primary violation of the Exchange Act, there is no basis to maintain a claim under Section 20(a). Parametric Tech., 300 F. Supp. 2d at 224 (holding that "where there is no liability under Section 10(b), it must follow that there is none under Section 20(a), regardless of an individual defendant's position or influence within a company").

Furthermore, the Section 20(a) claim fails because Plaintiffs have not adequately pled "culpable participation" on the part of any of the Individual Defendants. Indeed, the Amended Complaint simply contains no allegations sufficient to demonstrate that the individually named defendants knowingly, actively or even meaningfully participated in making statements with actual knowledge of their falsity. See SEC v. First Jersey Sec., Inc., 101 F.3d 1450, 1472 (2d Cir. 1996), cert. denied, 522 U.S. 812 (1997).[23]

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[23] The First Circuit has expressly confronted but declined to rule on whether culpable participation is an element of a Section 20(a) claim. See Stone & Webster, 414 F.3d at 196 n.6 (affirming in part and reversing in part dismissal of Section 10 and Section 20 claims and noting

(cont'd)

V. PLAINTIFFS' INSIDER TRADING ALLEGATIONS FAIL TO STATE A CLAIM

Without a primary violation of the Exchange Act, there also is no basis to maintain a claim for insider trading under Section 20(A). Parametric Tech., 300 F. Supp. 2d at 224 ("To establish an individual's liability under Section 20(A), the plaintiff must allege and prove a predicate violation of the Exchange Act.").[24]

Further, the Section 20(A) claim should be dismissed against Mr. Kellogg because Plaintiffs do not even allege that Mr. Kellogg traded Biogen Idec securities during the putative class period. (See Am. Compl. ¶¶ 387-92.)

CONCLUSION

For all the foregoing reasons, Defendants' motion to dismiss should be granted, and the Amended Complaint should be dismissed with prejudice.

Dated: November 15, 2006
Boston, Massachusetts

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Michael S. Hines, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on November 15, 2006.

Dated: November 15, 2006 /s/ Michael S. Hines
Michael S. Hines

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that "this Circuit has taken no position on the question whether a plaintiff must prove culpable participation on the part of the defendant in order to prevail" on control person claims).

[24] Even if Plaintiffs could establish a Section 10(b) violation -- and they cannot -- the 20(A) claim against Mr. Bucknum must nevertheless be dismissed because Plaintiffs do not purport to assert any predicate violation against Mr. Bucknum. (Am. Compl. ¶ 38.)

EXHIBIT A

Allegations Of "Why" Statements Are False And Misleading	**Supporting "Facts" (Citation to Am. Compl.)**	**PSLRA And Rule 9(b) Pleading Deficiencies (Citation To Brief)**
"Tysabri . . . was an immunosuppressive drug that left patients vulnerable to opportunistic infections" (Am. Compl. ¶ 97)	Research published in 1992 "concluded" that TYSABRI® prevented migration of immune cells to all organs of the body (¶¶ 98; 64-66)	That research made conclusions only as to immune response in the central nervous system (pp. 13-14)
"animal studies indicated that Tysabri worked to turn off the immune system" (Am. Compl. ¶ 97)	Animal studies conducted by Defendants "confirmed" that TYSABRI® prevented immune response in all organs of the body (¶¶ 101-03)	No particularized allegations of what was observed in animal studies or why those results support Plaintiffs' conclusions (p. 14)
"similar warnings were made in publications in scientific and medical journals regarding the severe immunosuppressive effects of Tysabri" (Am. Compl. ¶ 97)	Published studies by academic researchers hypothesized that TYSABRI® may impair immune response (¶¶ 104-17)	At most, those articles discuss only theoretical side effects, and none mention PML (pp. 15-16)
"scientific meetings were held where top scientists discussed the serious and inherent risks of Tysabri" (Am. Comp. ¶ 97)	Dr. Steinman "warned about the risks of opportunistic infections from Tysabri" at 2 conferences (¶ 118)	No particularized allegations that any Defendant attended those meetings or what was discussed (pp. 15-16)
"numerous serious opportunistic infections that had already occurred in patients participating in Tysabri clinical trials, confirmed prior data indicating how dangerous Tysabri actually is" (Am. Compl. ¶ 97)	(i) During the clinical trials, "at least 60 opportunistic infections" and numerous malignancies were reported (¶¶ 152-55) (ii) Two "confidential sources" believe that the misdiagnosis of PML in the Crohn's trials was "highly suspicious" (¶¶ 156-58)	(i) No allegations of when those infections occurred or if they were even caused by TYSABRI®. Further, malignancies were more common in placebo patients (pp. 16-18) (ii) "Confidential sources" do not describe any knowledge of Defendants, or first hand knowledge of that PML event (pp. 16-17)
Defendants failed to disclose to the FDA opportunistic infections observed during the TYSABRI® clinical trials (Am. Compl. ¶¶ 97, 129)	(i) During the Advisory Committee hearings, Defendants "admitted" that they observed "numerous" opportunistic infections (¶¶ 132-40) (ii) Biogen Idec and Elan "communicated regularly pursuant to the Collaboration Agreement (¶¶ 141-42; 68-79) (iii) "Confidential Sources" confirm that opportunistic infections occurred during TYSABRI® clinical trials (¶¶ 143-51)	(i) Only 8 opportunistic infections were observed during all clinical trials, and no particularized allegations that Defendants withheld safety information (pp. 21-23) (ii) No particularized allegations of what information was shared or when (pp. 24-25) (iii) Allegations are vague and non-specific, and do not allege that Defendants withheld safety information (pp. 23-24)